IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC,	§	
	§	
Plaintiff,	§	
	§	CAUSE NO. 2:11-CV-530-JRG
V.	§	
	§	**LEAD CASE**
LUPIN LTD., *et al.*,	§	
	§	
Defendants.		

MEMORANDUM OPINION AND ORDER

Before the Court are Plaintiff Allergan Sales, LLC's Opening Claim Construction Brief (Dkt. No. 107), Defendants' response (Dkt. No. 112), and Plaintiff's reply (Dkt. No. 116), concerning U.S. Patent Nos. 8,008,338 ("the '338 patent), 8,207,215 ("the '215 patent"); and 8,377,982 ("the '982 patent").

The Court held a hearing on August 6, 2013.

I. BACKGROUND

Plaintiff alleges infringement of the '338, '215, and '982 patents by Defendants through their manufacture and sale of generic versions of Plaintiff's Acular LS® product. All three patents are titled "Ketorolac Tromethamine Compositions for Treating or Preventing Ocular Pain." The patents generally relate to ophthalmic solutions containing 0.4% ketorolac tromethamine (as the active ingredient) and methods of treating a patient with such solutions to reduce or prevent ocular pain, particular post-surgical pain.

II. LEGAL PRINCIPLES

It is understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999). Claim construction is clearly an issue of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

To ascertain the meaning of claims, courts look to three primary sources: the claims, the specification, and the prosecution history. *Markman*, 52 F.3d at 979. The specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. *Id.* A patent's claims must be read in view of the specification, of which they are a part. *Id.* For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. *Id.* "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee's invention. Otherwise, there would be no need for claims. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992). Although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiments. *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

This Court's claim construction analysis is substantially guided by the Federal Circuit's decision in *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). In *Phillips*, the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. *Id.* The ordinary and customary meaning of a claim term "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention and that patents are addressed to, and intended to be read by, others skilled in the particular art. *Id.*

Despite the importance of claim terms, *Phillips* made clear that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in

which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of "a fully integrated written instrument." *Id.* at 1315 (quoting *Markman*, 52 F.3d at 978). Thus, the *Phillips* court emphasized the specification as being the primary basis for construing the claims. *Id.* at 1314-17. As the Supreme Court stated long ago, "in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims." *Bates v. Coe*, 98 U.S. 31, 38 (1878). In addressing the role of the specification, the *Phillips* court quoted with approval its earlier observations from *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998):

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316. Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. Like the specification, the prosecution history helps to demonstrate how the inventor and the Patent and Trademark Office ("PTO") understood the patent. *Id.* at 1317. Because the file history, however, "represents an ongoing negotiation between the PTO and the applicant," it may lack the clarity of the specification and thus be less useful in claim construction proceedings. *Id.* Nevertheless, the prosecution history is intrinsic evidence that is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims. *Id.*; *see Microsoft Corp. v. Multi-Tech Sys.,*

Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004) (noting that "a patentee's statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation").

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes. *Phillips*, 415 F.3d at 1319-24. According to *Phillips*, reliance on dictionary definitions at the expense of the specification had the effect of "focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." *Id.* at 1321. *Phillips* emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. *Id.*

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. *Id.* at 1323-25. Rather, *Phillips* held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant.

III. CONSTRUCTION OF AGREED TERMS

The Court hereby adopts the following constructions agreed to by the parties:

Term	Agreed to Construction
"0.4% ketorolac tromethamine"[1]	"0.4% w/v tromethamine salt of ketorolac"
"ketorolac tromethamine"[2]	"tromethamine salt of ketorolac"
"administration of the first composition results in increased ocular comfort as compared to the administration to the eye of the second composition"[3]	"the method of administration of the composition comprising 0.4% w/v ketorolac tromethamine results in increased ocular comfort as compared to the method of administration of the composition comprising 0.5% w/v ketorolac tromethamine"
"the first composition is as effective in treating ocular pain as the second composition"[4]	"the method of administration of the composition comprising 0.4% w/v ketorolac tromethamine is as clinically efficacious in treating ocular pain as the method of administration of the composition comprising 0.5% w/v ketorolac tromethamine"
"about 0.5% w/v ketorolac tromethamine"[5]	"approximately 0.5% w/v ketorolac tromethamine"
"administering at least once daily to an eye"[6] "the at least once daily administration to an eye" "administering four times daily to an eye" "the four times daily administration to an eye" "the administration to the eye of the second composition"	Plain and ordinary meaning

[1] This term appears in claims 3-9 of the '338 patent.
[2] This term appears in claims 6, 15 and 26 of the '982 patent.
[3] This term appears in claims 4, 5, 13, 14, 24 and 25 of the '982 patent.
[4] This term appears in claims 6, 15 and 26 of the '982 patent.
[5] This term appears in claims 3 and 12 of the '982 patent
[6] These terms appear in claims 1,3,4,5,10,12,13,14,22, 23,24 and 25 of the '982 patent.

IV. CONSTRUCTION OF DISPUTED TERMS IN THE '338 PATENT

a. "0.4% ketorolac""

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"0.4% w/v tromethamine salt of ketorolac"	"0.4% weight by volume of 5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid"

(Dkt. No. 103-1, 5/3/13 Updated Joint Claim Construction and Prehearing Statement, Ex. A at 1,3).

i. The Parties' Positions

Plaintiff submits that the term "0.4% ketorolac" appearing in claim 1 of the '338 patent should be construed to mean "0.4% w/v tromethamine salt of ketorolac"[7] Plaintiff argues that the intrinsic record shows that the terms "ketorolac" and "ketorolac tromethamine" were used interchangeably, with the first being used as a shorthand for the second, citing multiple such instances in both the patent specification and prosecution history. Plaintiff also relies on the un-rebutted extrinsic evidence declaration of Dr. Valentino Stella as showing that the two terms are used interchangeably by those skilled in the art. Finally, Plaintiff argues that Defendants' interpretation would exclude the preferred embodiment of the claimed invention.

Defendants, on the other hand, allege that the patents in suit define the term "ketorolac" to mean 5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, citing to the specification stating "this invention relates to topical ophthalmic compositions comprising 5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, otherwise known as ketorolac." ('338 Patent, col. 1, lines 14-17, Dkt. No. 107. Ex. 1). Defendants further argue that ketorolac tromethamine is a different chemical entity, with a different chemical structure and formula than "ketorolac." Defendants also contend that the terms "ketorolac" and "ketorolac tromethamine" are not used interchangeably in the patent specification. Finally, Defendants argue that the doctrine of claim

[7] The dispute over the meaning of the term "ketorolac" applies also to claim 10 of the '982 patent.

differentiation supports their interpretation, because different claims in the patent use the term "ketorolac" and "ketorolac tromethamine."

Plaintiff responds to Defendants' argument that ketorolac and ketorolac tromethamine are different chemical molecules, by pointing to dependent claims 3, 4 and 5, (depending from claim 1). The dependent claims specifically state that the composition includes "ketorolac tromethamine." According to Plaintiff, the term ketorolac in claim 1 must therefore encompass ketorolac tromethamine, and Defendants' construction of ketorolac would render claims 3, 4, and 5 not properly dependent on claim 1 since under Defendants' construction, ketorolac and ketorolac tromethamine are different chemical entities. Such a construction, Plaintiff submits, makes no sense in the context of the patent claims.

ii. Analysis

To act as its own lexicographer, a patentee must "clearly set forth a definition of the disputed claim term" other than its plain and ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1366 (Fed.Cir.2002). The patentee must "clearly express an intent" to redefine the term. *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed.Cir.2008). The Federal Circuit has described the standard for determining whether an inventor has provided such clear intent as "exacting." *Thorner v. Sony Computer Entertainment America, LLC,* 669 F.3d 1362, 1366 (Fed. Cir. 2012).

Defendants argue that the description "this invention relates to topical ophthalmic compositions comprising 5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, otherwise known as ketorolac" is such an express definition. However, the language used does not clearly rise to the level of lexicography. The Court declines to find the cited language meets this "exacting" standard and defines the term "ketorolac" as the free acid for one skilled in the art.

See, e.g., 3M Innovative Properties Co. v. Avery Dennison Corp., 350 F.3d 1365, 1369, 1371 (Fed.Cir.2004) (patentee acted as its own lexicographer when the specification stated: "'Multiple embossed' means two or more embossing patterns are superimposed on the web to create a complex pattern of differing depths of embossing."); *Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339 (Fed.Cir.2004) ("The solubilizers suitable according to the invention are defined below."). This is particularly so where the claims themselves, the remainder of the patent specification, and the prosecution history all indicate that the patentee used the terms "ketorolac" and "ketorolac tromethamine" interchangeably, with "ketorolac" acting as a shorthand expression for "ketorolac tromethamine."

First, the patent claims themselves show that Defendants' construction is logically flawed. As explained by Defendants, according to their definition "ketorolac" is a particular and distinct chemical structure and is a "chemical entity completely different than" ketorolac tromethamine. (Dkt. No. 112 at 11). Yet, claims 3, 4, and 5 of the '338 patent depend from claim 1. Each recites "the composition of claim 1 comprising 0.4% ketorolac tromethamine …." As argued by Plaintiff, "Claim 1 must cover the tromethamine salt, if dependent claims 3, 4 and 5 are to make any sense." *See, e.g., Allergan, Inc. v. Barr Labs., Inc.*, 501 Fed. App'x 965, 970 (Fed. Cir. 2013)(construing claim term $N(R^4)_2$ as covering non-identical R^4 substituents, so as to be consistent with dependent claims that covered non-identical R^4 substituents). The context in which the term "ketorolac" is used in claim 1 is highly instructive here, and shows that "ketorolac" as appearing in claim 1 must mean "ketorolac tromethamine." *Phillips*, 415 F.3d at 1313-14. ("the context in which a term is used in the asserted claim can be highly instructive," as

can other claims of the patent in question). Defendants' construction, which would exclude the tromethamine salt, is thus illogical in the context of the patent claims.[8]

Patent claims are part of a "fully integrated written instrument." *Markman*, 52 F.3d at 978. The specification is "always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1313, quoting *Vitronics*, 90 F.3d at 1582. Here, beginning with its title, the '338 patent clearly indicates that it is directed to "KETOROLAC TROMETHAMINE COMPOSITIONS." Starting in the "Background of the Invention" section, the specification repeatedly refers to ketorolac tromethamine and ketorolac interchangeably: *"Ketorolac tromethamine 0.5% (w/v) ophthalmic solution*, available from Allergan, Inc. under the tradename Acular®, is a safe and effective NSAID with proven analgesic and anti-inflammatory activity. The most common adverse event associated with the *0.5% ketorolac formulation* …." (Dkt. No. 107, Exh. 1 at col. 1, lines 34-38, emphasis added). The summary of the invention similarly uses the term "ketorolac" as shorthand for "ketorolac tromethamine": "of particular interest in relationship to this invention is the use of aqueous topical ophthalmic composition of *0.4% (w/v) ketorolac tromethamine* for the treatment of ocular pain … It is surprising that the *20% lower concentration of ketorolac* as compared to the above Acular® product …." (*See id.* at col. 1, line 64 to col. 2, line 5, emphasis added.) Thus, both in connection with the prior art Acular® product and the claimed invention,

[8] The Court finds that Plaintiff's proposed construction is far more plausible and logical in the context of the '338 patent claims and specification than Defendants' construction. Alternatively, under Defendants' interpretation, claims 3, 4 and 5 would define a product containing 0.4% w/v ketorolac free acid and additionally,0.4% w/v ketorolac tromethamine, a product that is nowhere described in the patent specification. The Court also finds such a construct is illogical in the context of the '338 patent specification. The Court notes that the PTO issued claims 3-5, and therefore must have believed that claims 3-5 were properly dependent on claim 1. Thus, the PTO could not have accorded the term "ketorolac" in claim 1 the definition proposed by Defendants. *See, e.g., Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1347 (Fed. Cir. 2001) ("we may presume that the examiner gave the terms in the proposed claim their "broadest reasonable interpretation consistent with the specification," since he was obliged to do so").

the inventors used the terms "ketorolac" and "ketorolac tromethamine" interchangeably in the patent specification.

Example 3 of the '338 patent reports on the results of a clinical study in which patients were administered 0.4% ketorolac tromethamine. As does the remainder of the patent specification, Example 3 uses "ketorolac" as a shorthand for the salt, referring to the "0.4% ketorolac formulation" (*id. at* col. 6, line 40), which in fact contained 0.4% ketorolac tromethamine, and to the patients who received 0.4% ketorolac tromethamine as the "ketorolac" group. (*Id.* at col. 6, line 7). The patent figures show a similar pattern of usage. *Compare id.* at col. 5, lines 28-44, reporting on clinical data using 0.4% ketorolac tromethamine, with Figure 1 "Effect of Ketorolac 0.4% on Pain Intensity …." Comparison of the text describing Figures 2-5 (*see id.* at col. 5, line 45 to col. 6, line 10) and the figures themselves again shows that the patentees used the term "ketorolac" as shorthand for "ketorolac tromethamine." Accordingly, the Court finds that the patent specification strongly supports interpreting the term "ketorolac" as used in claim 1 of the '338 patent (and claim 10 of the '982 patent), as "ketorolac tromethamine."

As discussed above, Defendants' construction would also exclude the tromethamine salt from the scope of claim 1. It would thus exclude the preferred (and arguably sole embodiment) of the invention, the 0.4% ketorolac tromethamine solution, described throughout the patent specification. A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583-84 (Fed. Cir. 1996). *See also Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in

this field would read the specification in such a way"). The Court finds that no such highly persuasive evidentiary support exists here.

The prosecution history also demonstrates that the patentee used the term "ketorolac" as shorthand for "ketorolac tromethamine." For example, after describing the commercially available 0.5% ketorolac tromethamine product (Acular®) (Dkt. No. 107, Exh. 2 at AGN-ACUL 0000064), the applicants then referred to the claimed composition as being "more comfortable [than] and as efficacious as the commercial ketorolac." (*Id.* at 0000065). Even the Board of Appeals adopted this shorthand usage, referring to the "0.4% ketorolac composition" although the claims before the Board all read "ketorolac tromethamine." (*Id.* at 436-441).

The prosecution history also contains scientific articles showing that those skilled in the art used the two terms interchangeably, providing further evidence of how one skilled in the art reading the '338 patent would understand the term "ketorolac" as used in claim 1. (*See id.* at 0000071-74 (referring to "Acular LS™ (ketorolac tromethamine ophthalmic solution 0.4%)" as "the reformulated ketorolac ophthalmic solution" as well as to the "ketorolac group"); 00000201-207 (referring to 0.4% and 0.5% ketorolac tromethamine solutions as 0.4% ketorolac and 0.5% ketorolac)). Similarly, a scientific study also submitted during prosecution indicates repeatedly in footnotes that the term "ketorolac" is shorthand for "ketorolac tromethamine" ("ketorolac = ketorolac tromethamine"). *Id.* at 253-284. The un-rebutted declaration of Dr. Stella, submitted on behalf of Plaintiff, also supports this conclusion.

Defendants argue that following the Board of Appeals' decision the applicants amended their claims in a way that clarifies that "ketorolac" must have a different meaning than "ketorolac tromethamine." More specifically, after the Board decision, the applicants submitted an amendment to their claims, cancelling then pending claim 1, which had read: "An aqueous

topical ophthalmic composition comprising from 0.35% to 0.45% ketorolac tromethamine." *Id.* at 443. Applicants explained that they were rewriting claim 2 "into independent form incorporating all of the limitations of the parent claims." *Id.* at 446. Before amendment, claim 2 had read: "The aqueous topical ophthalmic composition of claim 1 comprising 0.4% ketorolac tromethamine." After amendment claim 2 read: "An aqueous topical ophthalmic composition comprising 0.4% ketorolac." *Id.* at 443. Pending claim 2 ultimately issued as claim 1 of the '338 patent. Plaintiff responds that this amendment simply "implement[ed] the Board's March 31, 2011 decision," (*id.* at 446), in which the Board had adopted the shorthand usage of "ketorolac" for "ketorolac tromethamine."

Defendants' argument is not persuasive, particularly when weighed against the mass of evidence supporting the view that the patentee used the terms "ketorolac" and "ketorolac tromethamine" interchangeably. Moreover, prosecution disclaimer requires a clear and unequivocal disavowal of claim scope. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). The Court cannot find such a clear and unmistakable surrender here. While the applicants did amend pending claim 2 to delete the word "tromethamine," they also explained that claim 2 was being rewritten to incorporate all of the limitations of the parent claim. One such limitation was the term "tromethamine." This militates against a finding of clear and unmistakable surrender.

Finally, Defendants' cite the doctrine of claim differentiation as supporting their construction. Under that doctrine, a dependent claim is presumed to have different scope than the claim from which it depends. *Kraft Foods, Inc. v. International Trading Co.,* 203 F.3d 1362, 1366 (Fed. Cir. 2000). Defendants argue, for example, that claim 3 of the '338 patent depends from claim 1, and uses the term "ketorolac tromethamine." According to Defendants, Plaintiff's

construction of "ketorolac" would thus render the term "ketorolac tromethamine" as found in claim 3 redundant, or superfluous. The Court rejects Defendants' argument.

That doctrine is based on "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed.Cir.1999). "To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed.Cir.1987). However, the doctrine is less applicable, if at all, where other elements are present, differentiating one claim from another. *See, e.g., Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) ("A further reason for not applying the doctrine of claim differentiation in this case is that the Group I claims are not otherwise identical but for the references to pellets, linear extrudates, and composite compositions, and thus the district court's construction does not make the composite composition claims redundant."); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1326 (Fed. Cir. 2001) ("we further note that claim 3 embraces additional limitations not encompassed within claim 1 including, 'activating the communication of the record data of stored call charges from the mobile phone unit to the system provider.' Therefore, the doctrine of claim differentiation does not lead us to reach a different construction."); *Mantech Environmental Corp. v. Hudson Environmental Services, Inc.*, 152 F.3d 1368, 1376 (1998) ("Mantech's argument is flawed, however, because the steps defined in claim 4 of injecting potable water into the groundwater alone distinguish the scope of claim 4 from that of claim 1 and thus make Mantech's argument based on claim differentiation unavailing.")

Here, multiple different elements are found in claim 3 that are not present in claim 1 (as well as the other dependent claims cited by Defendants), thereby rendering Defendants' claim differentiation argument "unavailing." *Mantech*, 152 F.3d at 1376. Claim 3 requires, among other things, defined percentages of benzalkonium chloride, edetate disodium, Octxynol-40, and sodium chloride. None of these elements are found in claim 1. Thus, the doctrine of claim differentiation carries little, if any, weight here. Moreover, claim differentiation creates only a presumption. *Kraft*, 203 F.3d at 1368. Even if the Court were to accept Defendants' claim differentiation argument, the great weight of the evidence, including the written description and prosecution history, would overcome any presumption arising from claim differentiation. *Id.*

In light of the evidence of record, the Court finds that the term "0.4% ketorolac," as used in claim 1 of the '338 patent, would be understood by one skilled in the art to refer to "0.4% w/v ketorolac tromethamine." The parties have agreed that "ketorolac tromethamine" means "tromethamine salt of ketorolac." Therefore, "0.4% w/v ketorolac" also would be understood to mean **"0.4% w/v tromethamine salt of ketorolac."**[9] Similarly, the term "0.4% w/v ketorolac" as used in claim 10 of the '982 patent means **"0.4% w/v ketorolac tromethamine"** or **"0.4% w/v tromethamine salt of ketorolac."**

V. CONSTRUCTION OF DISPUTED TERMS IN THE '982 PATENT

a. "about 0.4% w/v ketorolac tromethamine"; "about 0.4% w/v ketorolac";

Plaintiff's Proposed Construction	Defendants' Proposed Construction
The term does not require construction, but if construed: "approximately 0.4% w/v tromethamine salt of ketorolac"	Indefinite

[9] Both Plaintiff and Defendant appear to agree that the term "0.4%" means "0.4% w/v."

(Dkt. No. 103-1, 5/3/13 Updated Joint Claim Construction and Prehearing Statement, Ex. A at 6, 9, 11, 12, 13, 14).

i. The Parties' Positions

The parties' dispute centers on the meaning of the word "about," as used in the phrases "about 0.4% w/v ketorolac tromethamine" and "about 0.4% w/v ketorolac." These phrases are found in '982 patent claims 1, 3, 10, and 12.[10]

Plaintiff argues that the term "about" is readily understood by one skilled in the art according to its plain and ordinary meaning. To the extent that any construction is necessary, Plaintiff contends that the term should be construed as "approximately." Plaintiff cites to a series of Federal Circuit and district court opinions construing "about" to mean "approximately." Finally, Plaintiff submits that although the term "about" appears in other claims in the patents in suit, including claims of the '215 patent and claim 21 of the '982 patent, Defendants do not argue indefiniteness for any of those claims.

Defendants submit that "about" renders these phrases, and thus these claims, indefinite. According to Defendants, during prosecution of the earlier issued '338 and '215 patents, the patentee originally presented claims with a range of "from 0.35% w/v to 0.45% w/v," of ketorolac tromethamine but then amended the claims to recite "0.4%" in the face of an obviousness rejection. Defendants argue that the inclusion of the term "about" is an attempt to recapture this claim scope to some degree, however, that it is unclear to what degree. It is this lack of clarity, Defendants submit, that renders the term "about" and thus these claims, indefinite.

[10] Prior to oral argument the parties withdrew their proposed constructions for the terms "0.4% w/v ketorolac tromethamine" and "0.5% ketorolac tromethamine" found in claims 1, 10, 22 and 23 of the '982 patent. Accordingly, these terms will be accorded their plain and ordinary meaning.

ii. Analysis

Indefiniteness is an invalidity defense that must be proven by clear and convincing evidence. *See, e.g., Young v. Lumenis, Inc.*, 492 F.3d 1336, 1347 (Fed. Cir. 2007). A claim is indefinite only when it is "not amenable to construction" or "insolubly ambiguous." *See, e.g., Biosig Instruments, Inc. v. Nautilus, Inc*, 715 F.3d 891, 897 (Fed. Cir. 2013). While Defendants argue indefiniteness, it is unclear whether they contend that the term "about" is not amenable to construction, or whether applying the plain and ordinary meaning of the term "about," the claim still "does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim," and is therefore insolubly ambiguous and invalid for indefiniteness. *See id.* (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 537 F.3d 1357, 1371 (Fed.Cir.2008)).

Defendants submit that the term "about" is an attempt to recapture subject matter that was found unpatentable during prosecution of the related '338 and '215 patents. There is insufficient evidence before the Court to conclude that patentees inserted the term "about" into the '982 patent in order to recapture subject matter relinquished during prosecution of the two related patents. Nor have Defendants provided the Court with any evidence, including expert testimony, regarding how one skilled in the art would interpret the term "about," or the alleged uncertainty of its breadth.

Defendants cite no authority indicating that a disclaimer in a first patent (assuming such a disclaimer exists here) would operate to disclaim subject matter in a subsequently prosecuted, albeit related patent. As a general rule, however, prosecution disclaimers do not carry over to subsequent patents. That is not surprising, as frequently the scope of patent claims in a patent family becomes progressively broader—patentees often accept narrower claims initially and then try to obtain broader claims in child applications. *See, e.g., Home Diagnostics, Inc. v. Lifescan,*

Incl., 381 F.3d 1352, 1358 (Fed. Cir. 2004); *Advanced Cardiovascular Sys, Inc.. v. Medtronic, Inc.*, 265 F.3d 1295, 1305-06 (Fed. Cir. 2001). A prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor. *See, e.g., Ventana Med. Sys. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1182 (Fed.Cir.2006) ("[P]rosecution disclaimer generally does not apply when the claim term in the descendent patent uses different language."); *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1141 (Fed.Cir.2003) ("When the applicant is seeking different claims in a divisional application, estoppel generally does not arise from the prosecution of the parent."). Moreover, when purported disclaimers made during prosecution are directed to specific claim terms that have been omitted or materially altered in subsequent applications, such disclaimers do not apply to the later patent. *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed.Cir.2007).

Here, the specific claim term "from 0.35% w/v to 0.45% w/v" does not appear in the '982 patent—it has been omitted or materially altered. *Id.* The Federal Circuit recently stated that the proper inquiry is whether the scope of the claim limitation is substantially the same in the subsequent application as it was in the earlier application. *Regents of the University of Minn. v. AGA Medical Corp.*, 717 F.3d 929, 944 (Fed. Cir. 2013). A disclaimer is carried forward to a subsequently prosecuted patent where there are only immaterial differences in claim scope. *Id.* Here, there is no indication that the term "about 0.4% w/v" has the same meaning or scope as "from 0.35% w/v to 0.45% w/v." There is more than an "immaterial difference" between the terms "about 0.4% w/v" and "from 0.35% w/v to 0.45% w/v." Accordingly, the Court declines to find that a disclaimer of "from 0.35% w/v to 0.45% w/v" from earlier prosecuted applications carries forward to the "about 0.4% w/v" limitation in the '982 patent.

Moreover, prosecution disclaimer requires a clear and unequivocal disavowal of claim scope. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). There was no such clear and unmistakable surrender in the earlier applications of the entirety of the range between 0.45% w/v and 0.35% w/v here, such that all values between those two numbers except "0.4% w/v" were disclaimed. Even if the Court found a disclaimer had occurred in the earlier applications, it would have been a disclaimer of the range between 0.35% and 0.45%, not of every value or set of values within that range except exactly 0.400%.

Defendants cite *Amgen, Inc. v. Chugai Pharma Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991) for the proposition that "[w]hen the meaning of claims is in doubt and there is close prior art, the claims are invalid." The term at issue in that case was "at least about 160,000," where the 160,000 value represented a specific activity measure for a biological molecule to be determined by bioassays. The district court had already determined that such bioassays "provide an imprecise form of measurement with a range of error." The range of error already inherent in the specific activity limitation coupled with the term "at least about" thus "served neither to distinguish the invention over the close prior art (which described preparations of 120,000 IU/AU), nor to permit one to know what specific activity values below 160,000, if any, might constitute infringement." *Id.* at 1217-18. Here, there is no evidence of any uncertainty regarding the term "about 0.4% w/v" of ketorolac tromethamine, or the ability of one skilled in the art to determine the amount of ketorolac tromethamine present in a topical ophthalmic product. The measure here is not an imprecise determination of the activity of a biological molecule; it is the ratio of weight/volume of ketorolac tromethamine present in solution. Moreover, the decision in *Amgen* was based on a fully developed factual record after trial, including expert testimony. In contrast, this case is at a preliminary stage and the Court is presented with no expert or other

testimony or any other evidence, only with attorney argument. For all of these reasons, the Court finds that Defendants have not met their burden of proving indefiniteness by clear and convincing evidence.

The Court interprets the term "about" according to its plain and ordinary meaning,[11] as "approximately." *See Merck & Co. v. Teva Pharms. USA, Inc.* 395 F.3d 1364, 1369-70 (Fed. Cir. 2005); *Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556, 1561 (Fed. Cir. 1994) *Biopolymer Eng'g, Inc. v. Imunocorp*, 2007 WL 4562592 *9-15 (D. Minn. Dec. 21, 2007); *Novartis Pharm. Corp. v. Apotex Corp.*, 2006 WL 626058 *10 (S.D.N.Y. 2006). The phrases "about 0.4% w/v ketorolac tromethamine" and "about 0.4% w/v ketorolac" mean **"approximately 0.4% w/v ketorolac tromethamine"** or **"approximately 0.4% w/v tromethamine salt of ketorolac."**

b. "the method reduces ocular pain and results in less ocular side effects as compared to"; "the method reduces ocular pain and burning and results in less ocular side effects compared to"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
The term does not require construction, but if construed: "the method reduces ocular pain compared to prior pain levels, and results in reduced ocular side effects as compared to the method of [the at least once daily administration to an eye of a second composition comprising 0.5% w/v ketorolac tromethamine]." "the method reduces ocular pain and burning compared to prior ocular pain and burning, and	"the 0.4% composition reduces ocular pain, which arises before the administration of the composition, as compared to the 0.5% composition and the 0.4% composition results in less ocular side effects (plural—at least two) from the administration of the composition as compared to [the 0.5% composition]." "the 0.4% composition reduces ocular pain and burning, which arises before the administration

[11] Defendants had previously argued that the term "about 0.5% w/v ketorolac tromethamine," also found in claims 3 and 12, was similarly indefinite. However, prior to oral argument the parties agreed that this term should be construed according to its plain and ordinary meaning, as "approximately 0.5% w/v ketorolac tromethamine." Such agreement undermines Defendants' argument that the term "about 0.4% w/v ketorolac tromethamine" is indefinite.

results in reduced ocular side effects as compared to the method of [the at least once daily administration to an eye of a second composition comprising 0.5% w/v ketorolac tromethamine.]"	of the composition, as compared to the 0.5% composition and the 0.4% composition results in less ocular side effects (plural—at least two) from the administration of the composition as compared to [the 0.5% composition]."

(Dkt. No. 103-1, 5/3/13 Updated Joint Claim Construction and Prehearing Statement, Ex. A at 20-22).

i. The Parties' Positions

The terms to be construed are found in '982 patent claims 1, 3, 10, 12, 22 and 23. The issues raised are (a) whether the 0.4% solution need only reduce ocular pain in the patient as compared to pain prior to treatment or must it also reduce ocular pain as compared to administering the 0.5% solution; and (b) whether the phrase "less ocular side effects" requires a reduction of two or more different side effects; or whether a reduction in the instances of a single side effect is sufficient.[12]

As to the first issue, Plaintiff submits that the claim language is clear and that by applying normal rules of syntax and grammar, the administration of the 0.4% solution need only result in reduction in ocular pain in a patient, rather than a reduction in pain as compared to the 0.5% solution. Plaintiff further argues that its construction is consistent with the patent specification. More specifically, Plaintiff cites to Example 3, describing a clinical trial involving only the 0.4% solution, and demonstrating that the 0.4% solution resulted in reduced ocular pain in patients. Plaintiff further points out that the patent nowhere states that administering the 0.4% solution reduces ocular pain to a greater extent than does the 0.5% solution. Finally, Plaintiff asserts that its construction does not improperly read a limitation into the claim, but rather simply clarifies what one skilled in the art would understand upon reading the patent specification.

[12] Defendants withdrew their indefiniteness argument prior to oral argument.

As to the second issue, Plaintiff argues that "less ocular side effects" was meant to include not only fewer kinds of side effects, but also a reduced frequency of side effects. Plaintiff points to Example 4 of the patent, describing a "comfort study" in which patients were asked to rate their "ocular discomfort" after administration of a 0.4% solution in one eye and a 0.5% solution in the other eye. According to Plaintiff, "ocular discomfort" equates to "side effects," and Example 4 shows that patients rated the 0.4% solution as causing less ocular discomfort (a cumulative score of 0.53) versus the 0.5% solution (a cumulative score of 0.87), and therefore less side effects. Thus, Plaintiff argues, the specification shows that "less ocular side effects" means at least a reduction in the frequency of at least one side effect. Finally, Plaintiff also points to the dependent claims, *e.g.*, claim 2, stating that "the side effects include at least one side effect from the group consisting of stinging, foreign body sensation or both." Plaintiff concludes the dependent claims show that a reduction in side effects simply requires that the frequency of at least one side effect is diminished as compared to the 0.5% solution.

Defendants argue that, as to the first issue, the 0.4% solution must reduce ocular pain in the patient as compared to the reduction in pain resulting from administering the 0.5% solution. Defendants submit that Plaintiff would improperly read into the claim the language "compared to prior ocular pain."

As to the second issue, Defendants argue that the plural phrase "side effects," requires that at least two side effects must be reduced. According to Defendant, the plain language of the claim requires administration to a "person" and therefore, the comparison in side effects must be in a person, not in a group of patients. This, Defendants submit, excludes the frequency of side effects argument by Plaintiff, which requires an analysis of side effects in a group. Defendants also argue that the dependent claims do not require that only a single side effect be present.

Finally, Defendants argue that had the patentee intended the claims to read as Plaintiff construes them, those claims would and could have been differently drafted.

ii. Analysis

The '982 patent is directed to treating or preventing pain using 0.4% ketorolac solutions, and the patent claims themselves are directed to methods of treating ocular pain. The claims themselves provide context for what is meant by "reduces ocular pain," and "reduces ocular pain and burning." Claim 1 is exemplary and is directed to a "method of treating ocular pain, the method comprising the step of administering at least once daily to an eye of the person a first composition comprising about 0.4% w/v ketorolac tromethamine, wherein the method reduces ocular pain …." According to the claim itself, the method treats and reduces ocular pain. The pain referred to in the claim is the reason for the treatment. Therefore, a reduction in pain must be, in the context of the claim itself, a reduction as compared to the pain prior to treatment.

The patent specification is directed to the treatment of ocular pain, especially after PRK (photorefractive keratectomy) surgery. The specification speaks repeatedly of clinical efficacy in treating ocular pain. One skilled in the art would understand clinical efficacy in treating ocular pain to mean reducing that pain in someone suffering ocular pain. Example 3 in the patent provides ample context for what is meant by "reduces ocular pain" or "reduces ocular pain and burning." That example discusses a clinical study on patients who had undergone PRK surgery. According to the example, those patients receiving 0.4% ketorolac reported greater and significantly faster pain relief than those receiving a placebo; the study concluded that the 0.4% ketorolac formulation was clinically effective in treating post-operative pain.

Nothing in the patent specification requires that administering the 0.4% solution to a patient results in reduced ocular pain as compared to the 0.5% solution. In fact, the specification

repeatedly states that the 0.4% and 0.5% solutions have comparable clinical efficacy. *See* Dkt No. 107, Exh. 12 at col. 1, lines 49-51; col. 2, lines 5-8 and 32-36; col. 7, lines 31-36. Defendants' construction would thus exclude the preferred (and arguably sole) embodiment of the invention, the 0.4% ketorolac tromethamine solution described throughout the patent specification. A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." *Vitronics,* 90 F.3d at 1583-84. No such highly persuasive evidentiary support exists here.

Patent claims are part of a "fully integrated written instrument." *Markman,* 52 F.3d at 978. The specification is "always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips,* 415 F.3d at 1313, quoting *Vitronics,* 90 F.3d 1576 at 1582. Consistent with the specification and the language of the claims themselves, to the extent that they require construction, the terms "reduces ocular pain" and "reduces ocular pain and burning" are construed to mean "reduces ocular pain compared to ocular pain before treatment" and "reduces ocular pain and burning compared to ocular pain and burning before treatment."

Defendants also seek to interpret the term "results in less ocular side effects" as being plural, requiring the reduction in "at least two" side effects. The patent claims themselves do not require a reduction in "at least two side effects." While the term "effects" is undoubtedly a plural, here it refers to a group of possible side effects that might occur in a patient population. Nothing in the patent claims or specification requires that an individual experience a lessening of two or more side effects as compared to the side effects they would suffer with the 0.5% solution. Nor do they require that an individual experience at least two less side effects,

regardless of degree, with the 0.4% solution than with the 0.5% solution.[13] Such a requirement would be inconsistent with the patent specification.

According to the specification, the "most common adverse events associated with use of the 0.5% ketorolac formulation is ocular irritation, primarily burning and stinging upon installation. Eliminating or reducing ocular irritation has the potential for improving tolerability, compliance, and effectiveness of treatment." Dkt. No. 107, Exh. 12, Col. 1, lines 40-45. The summary of the invention describes the "surprising discovery that reducing the concentration of ketorolac tromethamine reduces the occurrence of adverse events while maintaining clinical efficacy;" *id.* at Col. 1, lines 49-51, and similarly refers to the surprising discovery that the 0.4% solution "would reduce the incidence of adverse events." *Id.* at Col. 2, lines 5-8. The concentration of ketorolac used in the claimed method "is optimized to reduce side effects." *Id.* at Col. 2, lines 33-36. Example 3, at Table 4, shows that "adverse events were minor and infrequent for the group that received ketorolac tromethamine." Example 4 describes a study measuring "ocular discomfort" in which patients rated the relative level of burning/stinging. Burning and stinging are two types of ocular side effects. *See, e.g.*, claim 2. According to Example 4, patients scored the 0.4% solution as causing less ocular discomfort (a cumulative score of 0.53) versus the 0.5% solution (a cumulative score of 0.87). This equates to less ocular side effects in the group as a whole. Thus, the patent specification consistently refers to side effects as a group of effects measured in a patient population. The fact that the word "effects" is plural does not require that there be a reduction in "at least two" of these effects in a particular patient. Rather, the claims permit a comparison of the incidence (including severity) of one or more side effects between a group of patients receiving the 0.4% and 0.5% ketorolac products.

[13] As an example, the patent claims do not require that if a patient using the 0.5% solution experiences some degree of ocular irritation, ocular stinging, and ocular burning (three side effects), then when the patient uses the 0.4% solution that patient can only experience one of those three side effects.

Accordingly, the Court interprets the phrases "the method reduces ocular pain and results in less ocular side effects as compared to [the 0.5% solution]" and "the method reduces ocular pain and burning and results in less ocular side effects as compared to [the 0.5% solution]" as: **"the method reduces ocular pain as compared to ocular pain before treatment and results in a lower incidence of one or more ocular side effects as compared to [the 0.5% solution];"** and **"the method reduces ocular pain and burning as compared to ocular pain and burning before treatment and results in a lower incidence of one or more ocular side effects as compared to [the 0.5% solution]."**

VI. CONCLUSION

The Court adopts the constructions set forth in this opinion for the disputed terms of the '338 and '982 patents. There are no disputed terms for the '215 patent. The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

Within thirty (30) days of the issuance of this Memorandum Opinion and Order, the parties are hereby ORDERED, in good faith, to mediate this case with David Folsom, the mediator appointed in this case. As a part of such mediation, each party shall appear by counsel and by at least one corporate officer possessing sufficient authority and control to unilaterally make binding decisions for the corporation adequate to address any good faith offer or counteroffer of settlement that might arise during such mediation. Failure to do so shall be

deemed by the Court as a failure to mediate in good faith and may subject that party to such sanctions as the Court deems appropriate.

So ORDERED and SIGNED this 20th day of August, 2013.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE